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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/814,161	03/22/2001	M. Cynthia Goh	13626	2783

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DOWELL & DOWELL PC
SUITE 309
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EXAMINER

YANG, NELSON C

ART UNIT	PAPER NUMBER
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1641

DATE MAILED: 02/25/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.		Applicant(s)	
	09/814,161		GOH ET AL.	
	Examiner		Art Unit	
	Nelson Yang		1641	

-- Th MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 December 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 14-33 and 66 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 14-33 and 66 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Amendment

1. Applicants' amendments are acknowledged and have been entered.
2. The cancellation of claims 1-13, 34-65, and addition of claim 66 are acknowledged and have been entered.
3. Claims 14-33, and 66 are pending.

Rejections Withdrawn

4. Applicant's arguments, see p. 11, filed December 4, 2004, with respect to claim 15 have been fully considered and are persuasive. The objection of claim 15 has been withdrawn.
5. Applicant's arguments, see p. 11, filed December 4, 2004, with respect to claim 20 under 35 USC § 112, first paragraph, have been fully considered and are persuasive. The rejection of claim 20 under 35 USC § 112, first paragraph, has been withdrawn.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 14, 15, 17-24, 26, 29, 31-33 are rejected under 35 U.S.C. 102(b) as being anticipated by Everhart et al [US 6,060,256].

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Everhart et al teach a method comprising providing a substrate (dipstick) including a surface and on the surface a first pre-selected pattern of a first analyte specific pattern and at least a second pre-selected pattern of a second analyte-specific receptor (column 8, lines 25-30). Although the patterns are not directly formed on the surface of the substrate, they are located on the surface of the substrate, on metalized films. Everhart et al further teach contacting the surface of the substrate with the medium for a sufficient time to permit pre-selected analytes present in the medium to bind with their associated analyte specific receptors (column 18-21), illuminating the substrate and detecting, an image of diffracted light separate from the surface and analyzing the image of diffracted light for the presence of one or more of the pre-selected diffraction patterns (column 8, lines 1-3, 20-24, 35-37).

8. With respect to claim 15, Everhart et al teach a method in which a test strip comprising several metalized films each having a monolayer pattern allows for the detection of the presence of different analytes in a medium (column 8, lines 25-37). Although Everhart et al do not specifically recite the step of illuminating at least a part of each pattern, it would be an inherent step in determining the presence of analytes in a medium. Since Everhart et al teach that the presence of analytes is detected by illuminating the patterns observing the diffraction patterns that form (column 7, line 65 – column 8, line 7), each pattern present on the substrate would have to be illuminated in order to observe the optical diffraction pattern produced.

9. With respect to claim 17-19, Everhart et al teach a method in which an image of diffracted light prior to exposure of the substrate surface to a medium containing analytes of interest, or the baseline image, and an image of diffracted light after exposure to the medium are compared (column 4, lines 5-24). Specifically Everhart et al teach a method using disposable

biosensors, in which a transformation of a pattern from one pattern to another occurs upon binding of the analyte to the receptive material, which would require taking and recording images of diffracted light prior and after exposure to the medium.

10. With respect to claims 20-21, Everhart et al teach the transmitting of a light, such as a laser (column 3, lines 1-3). Everhart also teaches that the light can be monochromatic and in the visible spectrum (column 3, lines 11-17).

11. With respect to claim 22, the substrate is substantially transparent and the surface is illuminated from one side of the substrate, wherein the image of diffracted light from the substrate is detected on the opposite side of the substrate (column 8, lines 32-41).

12. With respect to claims 23-24 the substrate is reflecting and the surface is illuminated from one side of the substrate, wherein the image of diffracted light from the substrate is detected on the same side of the substrate (column 8, lines 32-41).

13. With respect to claim 26, Everhart et al teach a method in which the biosensor is placed on the inside surface of a container such as a glass vial, where the biosensor can then be visualized (column 8, lines 38-44), to determine whether there is microbial contamination.

14. With respect to claim 29, analyte-specific receptors include antibody-antigen binding pairs (column 6, lines 30-39).

15. With respect to claims 31-32, Everhart et al teach a method involving contacting the substrate with a standard material (polymer beads) that binds to the bound analytes (column 2, lines 25-27).

16. With respect to claim 33, Everhart et al teach a method where the medium is selected from the group consisting of blood, serum, plasma and urine (column 6, lines 60-61).

17. Claims 14, 15, 30, 31, and 32 are rejected under 35 U.S.C. 102(b) as being anticipated by Kumar et al [US 5,512,131].

Kumar et al teach a method comprising providing a surface where a variety of combinations of different stamping patterns, different pattern orientations and different stamping steps may be combined with a variety of pattern shapes and a variety of molecular species to produce a large variety of potential SAMs on a material surface (column 2, lines 3-20), where the SAMs may be comprised of different molecular species (column 3, lines 21-30) that selectively bind to various biological or other chemical species (column 11, lines 64 – column 12, line 9). Kumar et al further teach that the SAMs may be illuminated with coherent electromagnetic radiation, and a diffraction pattern observed, the intensity of the diffraction pattern used to quantitate the amount of immobilized label (column 16, lines 26-30).

18. With respect to claim 15, Kumar et al teach that a large region of regions may be illuminated and a diffraction pattern observed, the intensity of the diffraction pattern being used to quantitate the amount of immobilized label (column 16, lines 25-30).

19. With respect to claim 30, Kumar et al teach that the substrate is glass (column 15, line 66 – column 16, line 1).

20. With respect to claim 31, Kumar et al teach a sandwich assay in which a medium containing second binding partner that would bind to the analyte when it binds to functionalities on regions may be provided (column 16, lines 15-19).

21. With respect to claim 32, Kumar et al teach that the standard material can be a metal colloid, specifically gold (column 16, lines 23-24).

Claim Rejections - 35 USC § 103

22. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

23. Claim 16 is rejected under 35 U.S.C. 103(a) as being unpatentable over Everhart et al [US 6,060,256] in view of Yguerabide et al [US 6,586,193].

Everhart et al teach a method involving illuminating the patterns on a substrate, as discussed above. Everhart et al do not specifically teach illuminating the patterns one at a time. Yguerabide et al, however, teach the limitation of illuminate the patterns separately (column 98, lines 7-18), in order to avoid cross talk or other similar problems (column 97, lines 60-65). Therefore, it would have been obvious to illuminate the patterns one at a time, as taught by Yguerabide et al, in the method of Everhart et al, in order to avoid cross talk or other similar problems.

24. Claim 25 is rejected under 35 U.S.C. 103(a) as being unpatentable over Everhart et al [US 6,060,256] in view of Sandstrom et al [US 5,494,829].

Everhart et al teach a method of screening for analytes as discussed above. Everhart et al do not teach the step of rinsing and drying the substrate after contacting the substrate with a medium and prior to illumination. Sandstrom et al, however, do teach a step of rinsing and drying the substrate after an incubation period. Sandstrom et al further teach that this step is used to separate the unbound material from the reacted film (column 31, lines 20-24). Therefore it

would have been obvious to have a rinse and dry the substrate after contacting the surface of the substrate with the medium and prior to illumination, as taught by Sandstrom et al, in the method of Everhart et al, in order to separate unbound material from the reacted film.

25. Claims 27 and 66 are rejected under 35 U.S.C. 103(a) as being unpatentable over Everhart et al [US 6,060,256] in view of Kumar et al [US 5,512,131].

With respect to claim 27, Everhart et al teach a method in which the biosensor is placed on the inside surface of a container such as a glass vial, where the biosensor can then be visualized (column 8, lines 38-44), to determine whether there is microbial contamination, as discussed above. Everhart et al do not teach that intensities of selected regions of the resulting image of diffracted light are monitored as a function of time. Kumar et al, however, teach that by monitoring the intensity of the image of diffracted light as a function of time, the degree of contamination can be determined (columns 19-20, example 5). Although the contamination referred to by Kumar et al is condensation, a person of ordinary skill in the art would realize that the principle would also apply to microbial contamination. Therefore it would have been obvious to monitor the intensity of the image of diffracted light as a function of time, as taught by Kumar et al, in the method of Everhart et al, in order to determine the degree of contamination over time.

26. With respect to claim 66, Everhart et al teach a method in which an image of diffracted light prior to exposure of the substrate surface to a medium containing analytes of interest, or the baseline image, and an image of diffracted light after exposure to the medium are compared (column 4, lines 5-24), as discussed above. Everhart et al do not teach that the step of analyzing the images comprises analyzing for differences in intensity between the image of diffracted light

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and the baseline diffraction image. Kumar et al, however, teach that the intensity of the diffraction pattern can be used to quantitate the amount of immobilized label (column 16, lines 26-30). Therefore, it would have been obvious to analyze for differences in intensity between the image of diffracted light and the baseline diffraction image, as suggested by Kumar et al, in the method of Everhart et al, in order to quantitate the amount of immobilized analyte.

27. Claim 28 is rejected under 35 U.S.C. 103(a) as being unpatentable over Everhart et al [US 6,060,256] in view of Bouma et al [US 5,585,242].

Everhart et al teach a method of screening for analytes as discussed above. Everhart et al do not teach that the light illuminating the substrate is directed toward the substrate at an effective angle such that it undergoes total internal reflection from the substrate/medium interface. Bouma et al, however, teach that use of total internal reflection elements allows performing a homogenous assay (i.e. free of separation and wash steps) for members of specific binding pairs (column 2, lines 65-67). Therefore it would have been obvious for the light illuminating the substrate to undergo total internal reflection, as suggested by Bouma et al, in the method of Everhart et al, in order to perform a homogenous assay.

28. Claim 16 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kumar et al [US 5,512,131] in view of Yguerabide et al [US 6,586,193].

Kumar et al teach a method involving illuminating the patterns on a substrate, as discussed above. Kumar et al do not specifically teach illuminating the patterns one at a time. Yguerabide et al, however, teach the limitation of illuminate the patterns separately (column 98, lines 7-18), in order to avoid cross talk or other similar problems (column 97, lines 60-65).

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Therefore, it would have been obvious to illuminate the patterns one at a time, as taught by Yguerabide et al, in the method of Kumar et al, in order to avoid cross talk or other similar problems.

29. Claim 25 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kumar et al [US 5,512,131] in view of Sandstrom et al [US 5,494,829].

Kumar et al teach a method of screening for analytes as discussed above. Kumar et al do not teach the step of rinsing and drying the substrate after contacting the substrate with a medium and prior to illumination. Sandstrom et al, however, do teach a step of rinsing and drying the substrate after an incubation period. Sandstrom et al further teach that this step is used to separate the unbound material from the reacted film (column 31, lines 20-24). Therefore it would have been obvious to have a rinse and dry the substrate after contacting the surface of the substrate with the medium and prior to illumination, as taught by Sandstrom, in the method of Kumar, in order to separate unbound material from the reacted film.

30. Claim 28 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kumar et al [US 5,512,131] in view of Bouma et al [US 5,585,242].

Kumar et al teach a method of screening for analytes as discussed above. Kumar et al do not teach that the light illuminating the substrate is directed toward the substrate at an effective angle such that it undergoes total internal reflection from the substrate/medium interface. Bouma et al, however, teach that use of total internal reflection elements allows performing a homogenous assay (i.e. free of separation and wash steps) for members of specific binding pairs (column 2,

lines 65-67). Therefore it would have been obvious for the light illuminating the substrate to undergo total internal reflection, as suggested by Bouma et al, in the method of Kumar et al, in order to perform a homogenous assay.

Response to Arguments

31. Applicant's arguments with respect to claims 14-33 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

32. No claims are allowed.

33. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

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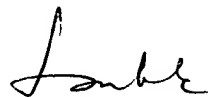
34. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nelson Yang whose telephone number is (571) 272-0826. The examiner can normally be reached on 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long V Le can be reached on (703) 305-3399. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

35. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Nelson Yang

Patent Examiner
Art Unit 1641



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02/20/04